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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,652	04/02/2004	Tadashi Hayashi	00862.018048	8200

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EXAMINER	
BOWERS, NATHAN ANDREW	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,652	Applicant(s) HAYASHI, TADASHI	
	Examiner Nathan A. Bowers	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>040204</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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1) Claims 1-6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braff (US 6692952) in view of Chou (US 20040224380).

With respect to claims 1 and 10, Braff discloses a target object modification apparatus that includes an aligner device comprising a plurality of electrodes (Figure 4:32) capable of manipulating the posture of a supplied target modification minute object (Figure 4:34). Column 6, lines 8-67 state that cells are added to the system and held at a desired location using an electric field trap. Column 7, lines 24-30 and column 18, lines 41-42 indicate that a feed means (Figure 15:152) is provided for supplying cells and modifiers to the aligner device. Braff, however, does not clearly state that the modifiers are injected using a separate injection means other than the cell feed means.

Chou discloses a microfluidic apparatus in which cells are held a desired location while being exposed to an array of different reagents. This is disclosed in paragraphs [0886]-[0888]. Cells are added to the system using a first feed means (Figure 95:2420), and various reagents and modifiers are injected using a plurality of separate injection means (Figure 95:2460).

Braff and Chou are analogous art because they are from the same field of endeavor regarding microfluidic cell modification apparatuses.

At the time of the invention, it would have been obvious to construct the apparatus of Braff in such a way to ensure that a separate injection means is provided for adding modifiers to the microfluidic system. As evidenced by Chou, this arrangement is considered to be well known in the art. The use of a separate modifier

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injection means would have been beneficial because it would have allowed one to add modifiers at essentially any time during the procedure.

With respect to claims 2 and 3, Braff and Chou disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Braff indicates in Figure 5 that an opening is provided for moving cells from the aligner device locations (Figure 5:110) to various storage reservoirs (Fractions 1-3). This is disclosed in column 6 lines 46-67.

With respect to claim 4, Braff and Chou disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Chou additionally teaches in paragraphs [0143]-[0145] that supply reservoirs are provided to hold cells and modifiers prior to injection.

With respect to claim 5, Braff and Chou disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Although Braff and Chou each disclose the use of cell reservoirs, modifier reservoirs and storage reservoirs, the references do not clearly teach that these reservoirs are detachable. However, it would have been obvious to construct them as separable components if this was determined to be advantageous. The construction of a system using individual, detachable components is considered to be well known in the art. Constructing a part so that it is

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separable from the remainder of the system generally does not result in the apparatus becoming patentable over the prior art. See MPEP 2144.04.

With respect to claim 6, Braff and Chou disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. Chou additionally discloses in Figure 95 the use of a plurality of chambers arranged in series that are fully capable of being used to stably fix the cells after exposure to the modifier. Chou teaches that the cells are allowed to contact a plurality of additional reagents following contact with the modifiers.

With respect to claim 8, Braff and Chou disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. In addition, Braff discloses that the aligner device has a structure in which a plurality of manipulation electrodes (Figure 4:32) are arranged around the cell. Braff additionally discloses that it is known to hold a cell within a recessed hole (Figure 1:12).

With respect to claim 9, Braff and Chou disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Braff also states that a plurality of aligner devices are arrayed to be able to simultaneously modify a plurality of cells. This is disclosed in columns 5 and 6.

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2) Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Braff (US 6692952) in view of Chou (US 20040224380) as applied to claim 1, and further in view of Hoffman (US 4989623).

Braff and Chou disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that a recovery mechanism is provided for cleaning and sterilizing the injection means.

Hoffman discloses an apparatus for cleaning the pipette tip of an injection means capable of introducing biological compounds into an analytical system. Hoffman teaches that the pipette tip (Figure 1:4) is automatically moved by a controller to a wash station (Figure 1:10) where the pipette tip is sterilized. This is disclosed in column 2, lines 19-39 and column 3, lines 1-15.

Braff, Chou and Hoffman are analogous art because they are from the same field of endeavor regarding biological analysis systems.

At the time of the invention, it would have been obvious to clean and sterilize the sample injection means disclosed by Braff. Hoffman teaches that disinfecting solutions such as bleach are well known in the art and capable of effectively cleaning an injection device in between uses. Hoffman additionally teaches that robotic pipette actuation systems are additionally advantageous because they allow one to automatically move an injection means from the analytical apparatus to a wash station.

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Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Dodgson (US 20040106189) and Harrison (US 6900021) references disclose the state of the art regarding microfluidic cell alignment devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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